IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ON APPEAL FROM THE PRIMARY EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application No.	:	10/755,038	Confirmation No.:	7887
Appellant	:	Avram Reuben Gold		
Filed	:	January 9, 2004		
Title	:	METHOD OF TREATING FUNCTIONAL SOMATIC SYNDROMES AND DIAGNOSING SLEEP DISORDERS BASED ON FUNCTIONAL SOMATIC SYNDROME SYMPTOMS		
Group Art Unit	:	3771		
Examiner	:	Shumaya B. Ali		
Customer No.	:	28289		

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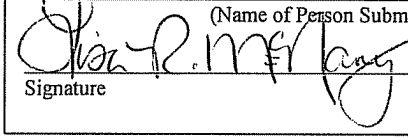
APPELLANT'S BRIEF UNDER 37 C.F.R. §41.37

Sir:

This Appeal Brief is submitted in support of the Notice of Appeal mailed on November 7, 2007 and received by the United States Patent and Trademark Office on that date. The Notice of Appeal appeals twice-rejected claims 1, 5, 6, 8-12, 16, 17, 19, and 20. The headings used hereinafter and that which is set forth under each heading are in accordance with 37 C.F.R. §41.37(c).

I hereby certify that this correspondence is being electronically submitted to the United States Patent and Trademark Office on January 11, 2008.

Lisa R. McNany
(Name of Person Submitting Paper)



Signature

01/11/2008
Date

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I. REAL PARTY IN INTEREST

The Research Foundation of the State University of New York is the Assignee of the entire right, title, and interest to the above-identified application and, as such, is the real party in interest in this Appeal. An Assignment dated May 6, 2004 and recorded at Reel/Frame 015463/0510 on June 16, 2004 in the United States Patent and Trademark Office confirms the assignment to the Research Foundation of the State University of New York.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences known to the Appellant, the Appellant's undersigned legal representative, or the Assignee of the above-identified application which will directly affect or be directly affected by or have a bearing on the Board's decision in this Appeal.

III. STATUS OF CLAIMS

Claims 1, 5, 6, 8-12, 16, 17, 19, and 20 are pending and are appealed.

Claims 2-4, 7, 13-15, 18, and 21-28 have been cancelled.

Claims 1, 5, 6, 11, 12, 16, and 17 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the teachings of United States Patent No. 5,954,048 to Thornton ("Thornton"), which was misidentified in the August 7, 2007 Office Action as "Threnton US 6,769,910 B1".

Claims 8, 9, 19, and 20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Thornton in view of United States Patent No. 6,752,766 to Kowallik et al. ("Kowallik").

Claim 10 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Thornton in view of United States Patent No. 5,378,686 to Bennett et al. ("Bennett").

Claims 1, 5, 6, 8-12, 16, 17, 19, and 20, which are the subject of this appeal, are reproduced in Appendix A, which is attached hereto. An original set of claims 21-28, which are referenced in this Appeal Brief on page 14, is reproduced in Appendix B.

IV. STATUS OF AMENDMENTS

All amendments to the claims in this application have been entered. The claims on appeal are the claims as amended by Appellant's Amendment in Anticipation of Appeal dated November 7, 2007. All of pending claims 1, 5, 6, 8-12, 16, 17, 19, and 20 were rejected for the fourth time in the August 7, 2007 Office Action.

V. SUMMARY OF CLAIMED INVENTION

The independent claims involved in this appeal are claims 1 and 12. The following is a concise explanation of the subject matter set forth claims 1 and 12. Unless otherwise noted, all references to specific paragraph numbers throughout this Appeal Brief refer to the paragraph numbers in the original Specification filed on January 9, 2004.

A method of treating functional somatic syndromes is claimed in claim 1. The method includes the step of determining whether a patient suffers from inspiratory airflow limitation during sleep. (Specification, ¶ [0010], ¶¶ [0021]-[0022]). The method further includes the step of identifying the patient suffering from inspiratory airflow limitation during sleep as having a functional somatic syndrome. (Specification, ¶¶ [0009]-[0010], ¶¶ [0020]-[0024]). The functional somatic syndromes are described in the Appellant's Specification as physical syndromes without an organic disease explanation, demonstrable structural changes, or established biochemical abnormalities. (Specification, ¶ [0005]). Finally, the method includes the step of treating the patient with an upper airway stabilization technique. (Specification, ¶¶ [0024]-[0033]). The upper airway stabilization technique involves the stabilization of the airway with, for example, positive airway pressure therapy. (Specification, ¶¶ [0025]-[0028]).

A method of treating functional somatic syndromes is claimed in claim 12. The method includes the step of determining whether a patient suffers from inspiratory airflow limitation during sleep. (Specification, ¶ [0010], ¶¶ [0021]-[0022]). The method further includes the step of identifying this patient as having one or more symptoms of a functional somatic syndrome. (Specification, ¶ [0011], ¶ [0017], ¶¶ [0023]-[0024]) In addition, the method includes the step of treating the patient with an upper airway stabilization technique, the technique comprising stabilization of the airway with positive airway pressure therapy as one embodiment. (Specification, ¶¶ [0024]-[0033]).

There are no other independent claims involved in this Appeal, nor are there other dependent claims that are argued separately in this Appeal. Therefore, Appellant is not required to provide a concise explanation of any dependent claim pursuant to 37 C.F.R. § 41.37(c)(1)(v).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether independent claim 1 was properly rejected under 35 U.S.C. § 103(a) over the teachings of Thornton?

B. Whether independent claim 12 was properly rejected under 35 U.S.C. § 103(a) over the teachings of Thornton?

VII. ARGUMENT

A. Claim 1 Was Not Properly Rejected Since the Required *Prima Facie* Case of Obviousness Under 35 U.S.C. § 103(a) Over Thornton Has Not Been Established.

Claim 1 stands rejected under 35 U.S.C. § 103(a) as being obvious over Thornton alone. Appellant respectfully submits that the August 7, 2007 Office Action ("Office Action") fails to establish a *prima facie* case of obviousness of claim 1 over Thornton and the rejection of this claim should be reversed.

When making a rejection under 35 U.S.C. § 103(a), the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Fritch*, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). Establishing a *prima facie* case of obviousness first requires the Examiner to resolve the factual inquires set forth in the case of *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). These inquires include: (1) determining the scope and content of the prior art, (2) ascertaining the differences between the claimed invention and the prior art, and (3) resolving the level of ordinary skill in the pertinent art. *Id.* at 17. Upon completing this analysis, the Examiner must then prove that, despite the differences between the prior art and the claimed invention, one skilled in the art would find it obvious to modify or combine the prior art in order to create the claimed invention. *KSR Int'l v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1397 (S.Ct. 2007). This determination "must be based on consideration of the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence." *Manual of Patent Examining Procedure*, (Rev. 6, Sept. 2007) § 716.01(d); *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

1. Scope and Content of the Prior Art

Thornton is directed to a device with an insertable oral section consisting of an upper arch and a lower arch. The arches are inserted into a user's mouth so that the upper arch engages the user's upper teeth and the lower arch engages the lower teeth. The upper arch and the lower arch are then connected by a hook and the hook forces the lower arch forward relative to the upper arch. The resulting forces cause the user's lower jaw to be positioned forward or displaced relative to the upper jaw. Such positioning of the lower jaw causes the user's breathing passageway to remain open and is known to treat certain sleep-related breathing

disorders like obstructive sleep apnea and, further, snoring. A continuous positive airway pressure (CPAP) system may also be associated with or connected to the device. Adjusting the air pressure from the CPAP system can act to increase the opening of the user's breathing passageway and may be used in cooperation with the lower jaw positioning feature to treat sleep related breathing disorders such as obstructive sleep apnea and, further, snoring.

2. Differences Between the Prior Art and the Claimed Invention

Claim 1 is directed to a method of treating functional somatic syndromes by: determining whether a patient suffers from inspiratory airflow limitation during sleep, identifying the patient as suffering from a functional somatic syndrome, and treating the patient with an upper airway stabilization technique. Appellant's claimed method is based on his pioneering recognition and discovery that inspiratory airflow limitation during sleep demonstrably plays a primary role in development of the functional somatic syndromes and, as a result, treatment of inspiratory airflow limitation via an upper airway stabilization technique, like positive airway pressure therapy as one provided example, "improves the symptoms/signs associated with the functional somatic syndromes". (Specification, ¶ [0066]). Accordingly, Appellant alone identifies a causal connection between inspiratory airflow limitation during sleep and the functional somatic syndromes and further teaches the corrective regimen of upper airway stabilization, whether by mechanical means and/or positive airway pressure therapy means, and the like.

As described by Appellant, functional somatic syndromes are defined as "physical syndromes without an organic disease explanation, demonstrable structural changes, or established biochemical abnormalities." (Specification, ¶ [0005]). A patient suffering from a functional somatic syndrome is usually characterized more by symptoms than by demonstrable and identifiable physical abnormalities. *Id.* Functional somatic syndromes, then, are a unique class of disorders for which current medical science has been unable to identify a unifying underlying cause. The foregoing definition of the functional somatic syndromes is corroborated by Dr. Mark Sanders, an expert in the field of Sleep Medicine, in his Declaration Under 37 C.F.R. § 1.132 ("Sanders Declaration") submitted on May 21, 2007. Dr. Sanders states that, "[Appellant's] disclosure correctly identifies a definition of functional somatic syndromes...that

comports with the medical literature relating to functional somatic syndromes." (Sanders Declaration, ¶ 5).

It is readily apparent from a close inspection of Thornton that this reference fails to teach or suggest any possible causal connection or linkage between restricted or limited inspiratory airflow during sleep and the functional somatic syndromes which may be addressed via upper airway stabilization pursuant to Appellant's disclosure. Only Appellant identifies the likely primary role of inspiratory airflow limitation during sleep and the functional somatic syndromes, (Specification, ¶ [0057]), and identifies corrective action or treatment of the inspiratory airflow limitation to modify the symptoms of functional somatic syndromes. (Specification, ¶ [0056]).

Obstructive sleep apnea and other similar disorders such as snoring, on the other hand, are commonly known to be caused by a fully or partially collapsed airway. Such sleep-disordered breathing has never been considered by those skilled in the art to be a functional somatic syndrome and is not part of any medical listing known to Appellant identifying or grouping the functional somatic syndromes. Treating patients known to experience a collapsed airway during sleep through the use of an oral device or positive airway pressure therapy is common in the Sleep Medicine field and is generally the subject of the Thornton reference. Appellant does not contest that the Thornton device is suitable for use in treating obstructive sleep apnea, snoring, and the like and may even be used in Appellant's claimed method for treating functional somatic syndromes as the Thornton device conventionally relieves, at least partially, an obstructed airway. However, it is abundantly clear from the plain text of Thornton that the disclosed CPAP-aided oral device is not directed to, nor is there any relevant teaching or suggestion in Thornton for, the treatment of the functional somatic syndromes.

As noted previously, it is the Appellant that has first identified the likely primary role of inspiratory airflow limitation during sleep and the functional somatic syndromes and proposed and developed a treatment regime in the form of stabilizing a patient's upper airway with positive airway pressure therapy and/or mechanical stabilization as specific examples. This discovery and methodological treatment implementation is a pioneering recognition and development in the medical field completely unrecognized by Thornton directly or through

reasonable implication or derivation of its teachings. Further evidence of this fact can be found in the Sanders Declaration. Dr. Sanders, a recognized expert in the field of Sleep Medicine, states that, "[t]he device disclosed in Thornton is intended to treat sleep disordered breathing such as snoring and sleep apnea using positive airway pressure therapy. The device is not intended to or disclosed in any way as being suitable for treating functional somatic syndromes." (Sanders Declaration, ¶ 8).

With the foregoing in mind, upon comparing the scope and content of the single piece of applied art and the claimed invention as embodied in claim 1, it can be concluded that there are fundamentally distinct and irreconcilable differences between the subject matter of claim 1 and the applied art (Thornton). First and foremost, Thornton is utterly silent on the subject of functional somatic syndromes, failing to mention the functional somatic syndromes (expressly or by implication) or patients suffering therefrom, much less a potential causal link between inspiratory airflow limitation during sleep and these syndromes. By extension, it is clear that Thornton does not (or cannot) disclose or suggest a step of identifying a patient determined to be suffering from inspiratory airflow limitation during sleep as having a functional somatic syndrome. Moreover, Thornton completely fails to teach or suggest a step of treating a patient identified as having a functional somatic syndrome with an upper airway stabilization technique. This latter step is based on Appellant's pioneering discovery that the functional somatic syndromes can likely be successfully treated through stabilization of a patient's upper airway with positive airway pressure therapy and/or mechanical stabilization as specific examples. The conventional obstructive sleep apnea/snoring treatment apparatus disclosed by Thornton is limited to treating a patient suffering from sleep-disordered breathing of known causation (i.e., a fully or partially collapsed airway) with a conventional oral device optionally coupled with continuous positive airway pressure therapy.

3. The Level of Ordinary Skill in the Pertinent Art

The foregoing enumerated differences between the Thornton disclosure and the subject matter of claim 1 are confirmed by Dr. Sanders (in his Declaration), who, as a medical doctor primarily practicing in the field of Sleep Medicine, is clearly one of ordinary skill in the pertinent art. Dr. Sanders states in his Declaration that, "[t]he device disclosed in Thornton is

intended to treat sleep disordered breathing such as snoring and sleep apnea...[and] is not intended to or disclosed in any way as being suitable for treating functional somatic syndromes." (Sanders Declaration, ¶ 8). Dr. Sanders further confirms that, "Thornton does not disclose or suggest a possible relationship between inspiratory airflow limitation during sleep and the functional somatic syndromes". *Id.* In light of the foregoing, it is thus clear that there exist fundamentally distinct differences between the Thornton reference and the subject matter recited by Appellant in claim 1.

4. The Office Action Fails to Support the Rejection of Claim 1 Under 35 U.S.C. § 103(a) Over Thornton

In order for an invention to be properly rejected under 35 U.S.C. § 103(a), there must be an explicit rationale explaining why, despite the differences between the applied art and the claimed invention, the claimed invention would have been obvious to one of ordinary skill in the art. *KSR*, 82 U.S.P.Q.2d at 1396. Because there has been no explicit rationale offered in the Office Action that explains why Appellant's claimed method, as embodied in claim 1, would have been obvious over Thornton despite the distinct differences present between the subject matter of claim 1 and Thornton, the rejection of claim 1 must be reversed.

As explained previously, Appellant has discovered a pioneering causal link between inspiratory airflow limitation during sleep and the functional somatic syndromes. This pioneering discovery led Appellant to develop a treatment method in which a patient determined to be suffering from inspiratory airflow limitation and identified as having a functional somatic syndrome is treated with an upper airway stabilization technique such as positive airway pressure therapy as one example. Thornton, on the other hand, is limited to the conventional treatment of obstructive sleep apnea and snoring, disorders of known causation, through the use of a conventional lower jaw repositioning oral device optionally coupled with a continuous positive airway pressure system. Despite these clear differences enumerated previously between Thornton and claim 1, the Office Action provides only a cursory and conclusionary treatment of claim 1 which appears on pages 3-4 of the Office Action. An explicit rationale explaining why, despite the differences between the applied art and the claimed invention, the claimed invention

would have been obvious to one of ordinary skill in the art is entirely missing in the Office Action. *KSR*, 82 U.S.P.Q.2d at 1396.

In the Office Action, it is contended that since Thornton teaches his oral device is for treating breathing disorders, and Appellant has listed sleep apnea and snoring as disorders/diseases that are considered functional somatic syndromes, Thornton teaches a device capable of providing treatment for a functional somatic syndrome. The foregoing reasoning in the Office Action fails on at least two accounts. First, Appellant has not, in fact, listed obstructive sleep apnea and snoring as disorders or diseases that are considered functional somatic syndromes. Appellant discussed obstructive sleep apnea and snoring in connection with a method of diagnosing *sleep disorders in general*, of which obstructive sleep apnea and snoring may be a symptom. (Specification, ¶¶ [0014-0015]). This method was the subject of original claims 21-28, which are not part of this appeal. Thus, the reasoning present in the Office Action in support of the rejection of claim 1 is fundamentally flawed and based on an incorrect reading of Appellant's disclosure relating to a possible method of diagnosing sleep disorders which may stem currently from Appellant's work in the field of functional somatic syndromes. This diagnostic method has been identified in the prosecution as a patentably distinct concept from the method addressed in claim 1 and was the subject matter of a Restriction Requirement issued on August 16, 2005. In response to this Restriction Requirement, Appellant elected to pursue the subject matter of independent claims 1 and 12 rather than the concept embodied in original claims 21-28. The diagnostic method in original claims 21-28 is not the subject of this Appeal and is properly the subject of a divisional application.

Second, whether or not the Thornton device is *capable* of treating a functional somatic syndrome is of no consequence to the patentability of the method claimed in claim 1. Claim 1 is directed to a method of treating functional somatic syndromes which may include a treatment device much like that disclosed by Thornton. Thornton discloses the use of an oral device optionally in conjunction with positive airway pressure therapy to treat obstructive sleep apnea and snoring. That this device is capable of being used in other, unknown methods does not render these new methods unpatentable since a new use of a known device is clearly patentable. 35 U.S.C. §§ 100-101; *see also In re King*, 801 F.2d 1324, 1327, 231 U.S.P.Q. 136,

138 (Fed.Cir. 1986) (affirming that "the discovery of a new use for an old structure based on unknown properties of the structure" could be "patentable to the discoverer as a process"). Moreover, Appellant is of the opinion that the Office Action has in fact put forward an inherency rejection but has re-couched this rejection in "obviousness" form by arguing that since the Thornton oral device is *capable* of treating a functional somatic syndrome it would inherently be obvious to do so. Such reliance on "inherency," however, is misplaced. The issued rejection is for obviousness under 35 U.S.C. § 103(a), and obviousness cannot be predicated on something allegedly inherently present in the prior art but unknown to those skilled in the art. *In re Spormann*, 363 F.2d 444, 448, 150 U.S.P.Q. 449, 452 (CCPA, 1966) ("That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown."). In any event, there is nothing "inherently" present in Thornton that would teach one skilled in the art to treat the functional somatic syndromes with an airway stabilization technique. Dr. Sanders particularly noted in this regard that "[t]he device disclosed in Thornton is intended to treat sleep disordered breathing such as snoring and sleep apnea...[and] is not intended to or disclosed in any way as being suitable for treating functional somatic syndromes." (Sanders Declaration, ¶ 8). Dr. Sanders further confirms that, "Thornton does not disclose or suggest a possible relationship between inspiratory airflow limitation during sleep and the functional somatic syndromes". *Id.*

Fundamentally, the Office Action makes a leap in logic that a recognized expert in the field of Sleep Medicine declares is not present in Thornton, namely, that one skilled in the art would immediately think to use the Thornton oral device to treat functional somatic syndromes. Only Appellant's disclosure provides this explicit teaching. Furthermore, Thornton similarly cannot satisfy the requirements of an anticipation rejection under 35 U.S.C. § 102 because it fails to disclose, inherently or otherwise, anything remotely connected with the functional somatic syndromes let alone the claimed steps of determining whether inspiratory airflow during sleep is present, identifying such a patient as having a functional somatic syndrome, and treating such a patient with upper airway stabilization technique(s). Thornton contains not even a modicum of disclosure related to the functional somatic syndromes which would support an anticipation rejection.

Next, the Office Action states that since it is known in the art that "diagnosis follows treatment" (it is assumed the Office Action meant to state "treatment follows diagnosis"), a physician has to identify a patient as having a functional somatic syndrome prior to prescribing treatment with Thornton's device. This rationale, however, fails to explain how Thornton's disclosure would have made it obvious to identify a patient suffering from inspiratory airflow limitation during sleep as having a functional somatic syndrome. As explained previously, Thornton is in no way directed to the treatment and diagnosis of functional somatic syndromes (overtly or "inherently"). Accordingly, Thornton also fails to disclose any connection between inspiratory airflow limitation during sleep and the functional somatic syndromes. Without knowledge of this relationship, which according to Dr. Sanders is not common medical knowledge in the field of Sleep Medicine, a physician would neither diagnose a patient suffering from inspiratory airflow limitation during sleep as having a functional somatic syndrome nor treat that patient with one or more upper airway stabilization techniques.

As further support that one skilled in the art would not find the subject matter of claim 1 to have been obvious over Thornton, Appellant refers to the Sanders Declaration. In his declaration, Dr. Sanders indicates that one skilled in the art reading Thornton would not be directed to use the Thornton device for treating patients suffering from functional somatic syndromes. (Sanders Declaration, ¶ 8). Dr. Sanders further indicates that the device disclosed in Thornton is only intended to treat sleep disordered breathing such as snoring and sleep apnea using positive airway pressure and is not disclosed as being suitable for treating functional somatic syndromes. *Id.* Dr. Sanders concludes by stating that until Appellant's recent disclosure, the use of a CPAP device to treat functional somatic syndromes was unknown and, consequently, untried and such a device would not have been used by one skilled in the art to treat a functional somatic syndrome, and it would be non-obvious to do so. *Id.*

In light of the foregoing remarks, the Office Action fails to set forth a *prima facie* case of obviousness as to claim 1. In view of the differences between the claimed subject matter and the applied art and lack of supporting rationale in the Office Action which does not explain with the requisite degree of clarity why one skilled in the art would find the method of treating

functional somatic syndromes recited in claim 1 obvious, the rejection of claim 1 should be reversed.

B. Claim 12 Was Not Properly Rejected Since the Required *Prima Facie* Case of Obviousness Under 35 U.S.C. § 103(a) Over Thornton Has Not Been Established.

Claim 12 also stands rejected under 35 U.S.C. § 103(a) for obviousness over Thornton alone. Appellant respectfully submits that the Office Action fails to establish a *prima facie* case of obviousness of claim 12 over Thornton and the rejection of this claim should also be reversed.

1. Scope and Content of the Prior Art

Because claim 12 stands rejected over Thornton as applied to claim 1, the first inquiry under the *John Deere* factors is the same as discussed *supra* in Section VII. A. 1.

2. Differences Between the Prior Art and the Claimed Invention

Claim 12 is directed to a method of treating functional somatic syndromes by: determining whether a patient suffers from inspiratory airflow limitation during sleep, identifying the patient as suffering from one or more symptoms of a functional somatic syndrome, and treating the patient with an upper airway stabilization technique. This method, like the method recited in claim 1, is based on Appellant's pioneering recognition and discovery that inspiratory airflow limitation during sleep demonstrably plays a primary role in development of the functional somatic syndromes and, as a result, treatment of inspiratory airflow limitation via an upper airway stabilization technique can be used to improve the symptoms associated with the functional somatic syndromes. Because functional somatic syndromes are disorders not usually associated with a known and identifiable physical abnormality, a patient suffering from a functional somatic syndrome or syndromes is often more easily identified by the physical symptoms he or she experiences than by any demonstrable structural change or organic disease. (Specification, ¶ [0005]). Examples of some of the symptoms most commonly associated with a functional somatic syndrome have been provided by Appellant, though one skilled in the art would understand this list to be non-exhaustive. (Specification, ¶ [0011]). Appellant's

pioneering discovery of a causal linkage between restricted or limited inspiratory airflow during sleep and the functional somatic syndromes has led to the development of the treatment method set forth in claim 12, which is slightly modified from claim 1, as this claim specifically calls out for identifying "symptom(s)" of a functional somatic syndrome rather than the full syndrome itself. Appellant's claim 12 identifies that once inspiratory airflow limitation during sleep is determined and one or more symptoms of a functional somatic syndrome is identified, the patient can be treated with an upper airway stabilization technique, such as positive airway pressure therapy in one embodiment.

Appellant's previous comments concerning Thornton respective to claim 1 are equally applicable to claim 12 and are incorporated herein by reference. As Thornton clearly fails to teach or suggest any potential causal connection or linkage between inspiratory airflow limitation during sleep and the functional somatic syndromes, it is readily apparent that this reference is likewise silent with respect to "symptoms" associated with the functional somatic syndromes according to claim 12. Accordingly, from the text of Thornton, it is abundantly apparent that the oral device disclosed therein is not directed to the treatment of a patient identified as having one or more symptoms of a functional somatic syndrome, which symptoms are completely unique from the symptoms associated with the disorders treated in Thornton, namely obstructive sleep apnea and snoring. Appellant's discovery that a patient identified as suffering from one or more symptoms of a functional somatic syndrome can be treated through stabilization of the patient's upper airway with, for example, positive airway pressure therapy is a pioneering recognition in the medical field that is completely unrecognized by Thornton directly or through reasonable implication of its teachings.

In light of the foregoing comments, upon comparing the scope and content of the single piece of applied art and the claimed invention as embodied in claim 1, it is clear that there are fundamentally distinct and irreconcilable differences between the subject matter of claim 12 and the applied art (Thornton). With respect to claim 12, as noted previously in connection with claim 1, Thornton is utterly silent on the subject of functional somatic syndromes, failing to mention the functional somatic syndromes (expressly or by implication) or patients suffering therefrom, and, moreover, is completely silent regarding any "symptoms" which could be

implied to be related to one or more of the functional somatic syndromes. Thornton does not even mention specific "symptoms" associated with obstructive sleep apnea and snoring which are ailments which the disclosed oral device is intended to treat. Without even enumerating a single such "symptom" one skilled in the art could not then even arguably extrapolate to a "symptom" of the functional somatic syndromes from the Thornton disclosure. Moreover, Thornton completely fails to teach or suggest a step of treating a patient identified as having one or more symptoms of a functional somatic syndrome with an upper airway stabilization technique. Furthermore, Thornton completely fails to teach or suggest a step of treating a patient identified as having one or more symptoms of a functional somatic syndrome with an upper airway stabilization technique since this step is based on Appellant's pioneering discovery that the functional somatic syndromes can likely be successfully treated through stabilization of a patient's upper airway with positive airway pressure therapy and/or mechanical stabilization as specific examples.

3. The Level of Ordinary Skill in the Pertinent Art

Appellant's comments in Section VII. A. 3. are incorporated herein by reference.

4. The Office Action Fails to Support the Rejection of Claim 12 Under 35 U.S.C. § 103(a) Over Thornton

Because there has been no explicit rationale offered in the Office Action that explains why Appellant's claimed method, as embodied in claim 12, would have been obvious over Thornton despite the distinct differences present between the subject matter of claim 12 and Thornton, the rejection of claim 12 must be reversed.

As explained previously in connection with claim 1, Appellant has discovered a pioneering causal link between inspiratory airflow limitation during sleep and the functional somatic syndromes. This pioneering discovery led Appellant to develop a treatment method in which a patient determined to be suffering from inspiratory airflow limitation and identified as having a functional somatic syndrome is treated with an upper airway stabilization technique such as positive airway pressure therapy as one example. Claim 12 extends this pioneering link to identifying one or more symptoms of a functional somatic syndrome rather than the syndrome itself but is otherwise similar in scope to claim 1. As with claim 1, the Office Action provides

only a cursory and conclusionary treatment of claim 12 which appears on pages 5-6 of the Office Action. An explicit rationale explaining why, despite the differences between the applied art and the claimed invention, the claimed invention would have been obvious to one of ordinary skill in the art is entirely missing in the Office Action. *KSR*, 82 U.S.P.Q.2d at 1396.

Because the rationale applied in the Office Action in rejecting claim 12 mirrors that provided in the rejection of claim 1, Appellant incorporates herein the arguments presented *supra* in Section VII. A. 4. Appellant submits that the rationale presented in the Office Action in rejecting claim 12 suffers from the same deficiencies as that offered in rejecting claim 1 since, as previously explained, Thornton similarly fails to disclose or suggest any potential link between inspiratory airflow limitation during sleep, one or more symptoms of the functional somatic syndromes, and a treatment method using upper airway stabilization. Consequently, Appellant's previous arguments are adequate to establish that the rejection of claim 12 should also be reversed and will not be repeated here.

In light of the foregoing remarks, the Office Action fails to set forth a *prima facie* case of obviousness as to claim 12. In view of the differences between the claimed subject matter and the applied art and lack of supporting rationale in the Office Action which does not explain with the requisite degree of clarity why one skilled in the art would find the method of treating functional somatic syndromes recited in claim 12 obvious, the rejection of claim 12 should be reversed.

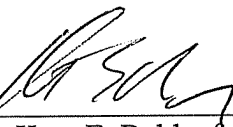
VIII. CONCLUSION

In view of the foregoing, it is respectfully submitted that the rejections of claims 1, 5, 6, 8-12, 16, 17, 19, and 20 under 35 U.S.C. § 103(a) are improper, and all of the pending claims are allowable. Appellant therefore respectfully urges the Board to reverse the Examiner's final rejections of these claims.

Payment of $510.00 to cover the large entity fee for filing an Appeal Brief Under 37 C.F.R. §41.37 accompanies this Appeal Brief. The Commissioner for Patents and Trademarks is hereby authorized to charge any additional fees which may be required to Deposit Account No. 23-0650. Please refund any overpayment to Deposit Account No. 23-0650.

Respectfully submitted,

THE WEBB LAW FIRM

By 

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APPENDIX A - PENDING CLAIMS

1. A method of treating functional somatic syndromes comprising the steps of:

determining whether a patient suffers from inspiratory airflow limitation during sleep;

identifying such a patient as having a functional somatic syndrome; and

treating such a patient with an upper airway stabilization technique;

wherein treating such a patient with an upper airway stabilization technique comprises stabilizing the airway with positive airway pressure therapy.

2.-4. (Cancelled).

5. The method as claimed in claim 1, wherein the positive airway pressure therapy is selected from the group consisting of: continuous positive airway pressure, bi-level positive airway pressure, and auto-titrating positive airway pressure.

6. The method as claimed in claim 1, wherein identifying a patient as having a functional somatic syndrome includes identifying a symptom of the functional somatic syndrome, wherein the symptom is selected from the group consisting of: chronic fatigue, irritable bowel, migraine headaches, tension headaches, temporomandibular joint pain, premenstrual pain, sleep-onset insomnia, sleep maintenance insomnia, unrefreshing sleep, EEG evidence of sleep fragmentation, bruxism, muscle pain, muscle tenderness, heartburn, abdominal pain, abdominal urgency, diarrhea, depression, orthostatic syncope, alpha-delta sleep.

7. (Cancelled).

8. The method as claimed in claim 1, further comprising the step of categorizing a patient who has an inspiratory airflow limitation during sleep of approximately

fifty-one to one-hundred percent of waking levels as an upper airway resistance syndrome (UARS) patient.

9. The method as claimed in claim 1, further comprising the step of categorizing a patient who has an inspiratory airflow limitation during sleep of approximately zero to fifty percent of waking levels as an obstructive sleep apnea/hypopnea (OSA/H) patient.

10. The method as claimed in claim 1, further comprising the step of observing alpha-delta sleep of such a patient to diagnose the functional somatic syndrome.

11. The method as claimed in claim 1, wherein the functional somatic syndrome is selected from the group consisting of: chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome, migraine headaches, tension headaches, temporomandibular joint syndrome, Gulf War syndrome, premenstrual syndrome, multiple chemical sensitivity, sick building syndrome, repetition stress injury, side effects of silicone breast implants, chronic whiplash, and restless leg/periodic limb movement syndrome.

12. A method of treating functional somatic syndromes comprising the steps of:

determining whether a patient suffers from inspiratory airflow limitation during sleep;

identifying such a patient as having one or more symptoms of a functional somatic syndrome; and

treating such a patient with an upper airway stabilization technique;

wherein treating such a patient with an upper airway stabilization technique comprises stabilizing the airway with positive airway pressure therapy.

13.-15. (Cancelled).

16. The method as claimed in claim 12, wherein the positive airway pressure therapy is selected from the group consisting of: continuous positive airway pressure, bi-level positive airway pressure, and auto-titrating positive airway pressure.

17. The method as claimed in claim 12, wherein the one or more symptoms symptom of the functional somatic syndrome are selected from the group consisting of: chronic fatigue, irritable bowel, a migraine headache, a tension headache, temporomandibular joint pain, premenstrual pain, sleep-onset insomnia, sleep maintenance insomnia, unrefreshing sleep, EEG evidence of sleep fragmentation, bruxism, muscle pain, muscle tenderness, heartburn, abdominal pain, abdominal urgency, diarrhea, headaches, depression, orthostatic syncope, alpha-delta sleep.

18. (Cancelled).

19. The method as claimed in claim 12, further comprising the step of categorizing a patient who has an inspiratory airflow limitation of approximately fifty-one to one-hundred percent of waking levels as an upper airway resistance syndrome (UARS) patient.

20. The method as claimed in claim 12, further comprising the step of categorizing a patient who has an inspiratory airflow limitation of approximately zero to fifty percent of waking levels as an obstructive sleep apnea/hypopnea (OSA/H) patient.

21.-28. (Cancelled).

APPENDIX B - ORIGINAL CLAIMS 21-28

21. (Previously Cancelled) A method of diagnosing a sleep disorder comprising the steps of:

determining whether a patient suffers from one or more symptoms of a functional somatic syndrome; and

diagnosing such a patient as having sleep-disordered breathing.

22. (Previously Cancelled) The method as claimed in claim 21, further comprising the steps of diagnosing the patient as a moderate to severe obstructive sleep apnea/hypopnea (OSA/H) patient if alpha-delta sleep is not substantially present, and treating such a patient with an airway stabilization technique.

23. (Previously Cancelled) The method as claimed in claim 21, further comprising the steps of diagnosing the patient as an upper airway resistance syndrome (UARS) or mild to moderate obstructive sleep apnea/hypopnea (OSA/H) patient if alpha-delta sleep is substantially present and treating such a patient with an airway stabilization technique.

24. (Previously Cancelled) The method as claimed in claim 21, further comprising treating such a patient with an airway stabilization technique.

25. (Previously Cancelled) The method as claimed in claim 24, wherein the airway stabilization technique comprises stabilizing the airway with a mechanical stabilization, the mechanical stabilization selected from the group consisting of:

an oral appliance adapted to control a position of an anatomical feature of a patient;

a tissue distending device adapted to be located externally and coupled to such a patient so as to distend tissue associated with such a patient's airway; and

a stimulation device adapted to apply a stimulating energy to a patient.

26. (Previously Cancelled) The method as claimed in claim 24, wherein treating such a patient with an airway stabilization technique comprises stabilizing the airway with positive airway pressure therapy.

27. (Previously Cancelled) The method as claimed in claim 26, wherein the positive airway pressure therapy is selected from the group consisting of: continuous positive airway pressure, bi-level positive airway pressure, and auto-titrating positive airway pressure.

28. (Previously Cancelled) The method as claimed in claim 21, wherein the one or more symptoms of a functional somatic syndrome is selected from the group consisting of: chronic fatigue, irritable bowel, migraine headaches, tension headaches, temporomandibular joint pain, premenstrual pain, sleep-onset insomnia, sleep maintenance insomnia, unrefreshing sleep, EEG evidence of sleep fragmentation, bruxism, muscle pain, muscle tenderness, heartburn, abdominal pain, abdominal urgency, diarrhea, depression, orthostatic syncope, alpha-delta sleep.

APPENDIX C—EVIDENCE

Declaration of Dr. Mark Sanders submitted May 21, 2007.	Made of record by the Examiner during prosecution as evidenced by Office Action of August 7, 2007.
Restriction Requirement issued August 16, 2005.	Issued by the Examiner and made of record August 16, 2005.
Response to August 16, 2005 Restriction Requirement dated September 15, 2005.	Made of record by the Examiner as acknowledged in the November 29, 2005 Office Action.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/755,038	Confirmation No.:	7887
Applicant	:	Avram Reuben Gold		
Filed	:	January 9, 2004		
Title	:	METHOD OF TREATING FUNCTIONAL SOMATIC SYNDROMES AND DIAGNOSING SLEEP DISORDERS BASED ON FUNCTIONAL SOMATIC SYNDROME SYMPTOMS		
Group Art Unit	:	3771		
Examiner	:	Adam Curtis Brandt		

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. §1.132

Sir:

I, Mark H. Sanders, hereby declare and state as follows:

1. I am a graduate of the State University of New York Upstate Medical Center, earning my Medical Doctorate in 1974. I completed an Internship and a Residency in Medicine at the Emory University Affiliated Hospitals in 1977 and was a Fellow in Pulmonary Medicine at the Emory University Affiliated Hospitals in 1978. From 1978 until 1980, I was a Fellow in Pulmonary and Critical Care Medicine and Pulmonary Research at the University of Oklahoma Health Sciences Center. My specialty certifications include the American Board of Sleep Medicine, the American Board of Internal Medicine, and the Subspecialty of Pulmonary Medicine. In addition, I was formerly certified in Critical Care Medicine.

2. From 1982 until 1995, I was the Medical Director of the Pulmonary Sleep Evaluation Laboratory at the University of Pittsburgh Medical Center. From 1982 until the present, I have been the Director of the Pulmonary Sleep Research and Control of Breathing Laboratory at the University of Pittsburgh. From 1991 until 2002, I was Chief of the Pulmonary

Sleep Disorders Program at the University of Pittsburgh Medical Center and from 2003 until the present, I have been the Director of Research of this program. From 1980 until 1982, I was an Assistant Professor of Medicine and Director of the Medical Intensive Care Unit at the University of Cincinnati College of Medicine. From 1982 until 1989, I was an Assistant Professor of Medicine at the University of Pittsburgh School of Medicine. From 1989 until 1996, I was an Associate Professor of Medicine (primary appointment) and Anesthesiology (secondary appointment) at the University of Pittsburgh School of Medicine. From 1996 until the present, I have been a Professor of Medicine and Anesthesiology at the University of Pittsburgh School of Medicine.

3. I have read the subject Application of which Dr. Avram Gold is the inventor, together with the November 21, 2006 Office Action and the documents cited against the claims of the Application, particularly Pantino (U.S. Patent No. 6,769,910) and Thornton (U.S. Patent No. 5,954,048).

4. I have reviewed the rejections in the November 21, 2006 Office Action ("Office Action") alleging that the Application is enabling, as stated in the Office Action with regard to a "method of treating the particular functional somatic syndrome of fibromyalgia, UARS and OSA/H", but does not reasonably provide enablement for treating other functional somatic syndromes without undue or unreasonable experimentation.

5. I conclude that the Application, when read by one skilled in the art, would allow such person to practice the full scope of the claims without undue or unreasonable experimentation. Dr. Gold's disclosure correctly identifies a definition of functional somatic syndromes (FSS) as being physical syndromes without an organic disease explanation, demonstrable structural changes, or established biochemical abnormalities that comports with the medical literature relating to functional somatic syndromes, (See paragraph [0005] of the Application). He further correctly identifies a medical literature-identified listing of functional somatic syndromes to include: chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome, migraine headaches, tension headaches, temporomandibular joint syndrome, premenstrual syndrome, multiple chemical sensitivity, sick building syndrome, repetition stress injury, side effects of silicone breast implants, Gulf War syndrome, chronic whiplash, and restless leg/periodic limb movement syndrome, (See paragraph [0005] of the Application). Further, one skilled in the medical art, namely, a medical doctor, would be able to diagnose a

patient as suffering from a functional somatic syndrome based on the appearance of one or more of these conditions without a medical explanation. Dr. Gold's Application clearly articulates his thesis statement that inspiratory airflow limitation during sleep has a likely underlying or unifying role in the development of the functional somatic syndromes and can be treated by correcting inspiratory airflow limitation during sleep, (See paragraphs [0009], [0022] and [0057] of the Application). This is accomplished as disclosed in the Application by stabilizing the upper airway of the patient using one or more kinds of upper airway stabilization devices or techniques, (See paragraphs [0025] of the Application). He enumerates clearly in several locations in the Application, (See, for example, paragraphs [0022], [0056], [0066] of the Application) that treatment of inspiratory airflow limitation during sleep may be used to treat the functional somatic syndromes and is not confined to treating any one of the individual functional somatic syndromes, such as fibromyalgia. Exemplary devices/apparatus for use in upper airway stabilization via positive airway pressure therapy are provided in the Application in paragraphs [0026], (CPAP) and [0029], (mechanical stabilization) as examples. Based on the foregoing evidence, one skilled in the art would understand from this Application that the inventor claims that inspiratory airflow limitation during sleep has a likely underlying or unifying role in the development of the functional somatic syndromes and treating or correcting inspiratory airflow limitation during sleep is likely to be effective in addressing this potential root cause of functional somatic syndromes. Moreover, based on the foregoing evidence, one skilled in the art would be able to practice Dr. Gold's teaching because multiple common or well-known upper airway stabilization techniques are described in the Application in connection with the claimed treatment methods. Accordingly, I conclude that the Application teaches that a patient suffering from inspiratory airflow limitation followed by an identification or determination of the presence of a functional somatic syndrome (or one or more symptom thereof) could be treated by the methods and apparatus disclosed in the Application without undue or unreasonable experimentation. It would be understood by one skilled in the art, after reading Dr. Gold's disclosure, that the disclosed methods and apparatus are not intended to be limited to the treatment of fibromyalgia as in Example II but are intended to treat functional somatic syndromes generally once inspiratory airflow limitation during sleep has been identified in a patient. One skilled in the art would not be required to perform undue experimentation based on this disclosure to apply the claimed methods and apparatus to a specific functional somatic

syndrome or syndromes and would recognize that the specific fibromyalgia example, Example II, beginning on page 17 of the Application, is merely a representative example for treating any individual functional somatic syndrome, as this is the intent of Dr. Gold's disclosure. I find that it is quite clear that the methods and apparatus identified in Dr. Gold's disclosure may be used, without undue or unreasonable experimentation, to treat a patient identified as suffering from any of the functional somatic syndromes or symptom(s) thereof once upper airway limitation during sleep has been determined in the patient.

6. I have reviewed the rejections in the Office Action alleging that the claims are obvious over Pantino in view of Thornton. In particular, I have reviewed the position set forth in the Office Action that Pantino discloses a method of treating functional somatic syndromes including the steps of identifying a patient as having a functional somatic syndrome and treating the patient with an upper airway stabilization technique, and that it would have been obvious to include the continuous positive airway pressure ("CPAP") stabilization technique taught by Thornton in the Pantino method to treat the patient. I have also reviewed the position set forth in the "Response to Arguments" outlined in the Office Action, which alleges that the combination of Pantino's mechanical oral appliance modified with Thornton's CPAP device is capable of treating the functional somatic syndromes and therefore renders the claimed methods obvious and unpatentable.

7. Based on my reading of the Pantino disclosure, this patent is limited to an orally-inserted device for improving breathing, and abating or completely alleviating snoring sounds, temporomandibular joint syndrome ("TMJ"), and bruxism while sleeping. It is well-known that such oral devices or appliances often have a benefit of treating the physical symptoms associated with TMJ and bruxism due to the fact that the oral appliance repositions the lower jaw, separates the upper and lower jaw, and fixes the lower jaw relative to the upper jaw while sleeping. It is my belief that one skilled in the art would understand that the Pantino disclosure and the oral appliance therein is directed primarily to treatment of sleep disordered breathing by the physical repositioning of the lower jaw and that the additional benefit of this repositioning is the reduction of the symptoms of TMJ and bruxism in the patient by "minimizing the negative effects of a static positioning of the: 1) teeth and related muscles and ligaments", (See Pantino column 4, lines 63-64). Accordingly, there is nothing in the Pantino disclosure relating to a causal connection or linkage between inspiratory airflow limitation

during sleep as a likely underlying or unifying cause of the functional somatic syndromes as per Dr. Gold's disclosure and, thus, no recognition on the part of Pantino that his mechanical oral device would in any way be applicable to or capable of treating the functional somatic syndromes. The fact that the Pantino oral appliance can additionally treat the symptoms of TMJ and bruxism in no way leads one skilled in the art to conclude that it can be used to treat functional somatic syndromes generally. Thus, the claimed treatment methods are not taught or suggested. It is further clear to me that the Pantino device is a mechanical device and one skilled in the art would not be motivated in any way to add a positive airway pressure component to this mechanical device for treatment of TMJ and bruxism as the mechanical oral device itself provides the benefit of treating the symptoms associated with TMJ and bruxism by repositioning the lower jaw (e.g., mandible). Based on the teachings of Pantino (limited to a mechanical oral appliance), the addition of a positive airway pressure therapy component would add nothing to the treatment of TMJ and bruxism and would be unnecessary. Finally, I respectfully disagree with the general contention in the Office Action that it would be obvious to one skilled in the art to add a positive airway pressure component to the Pantino oral appliance for the treatment of the functional somatic syndromes. Only Dr. Gold's Application identifies a causal connection between inspiratory airflow limitation during sleep and the functional somatic syndromes and further teaches the corrective regimen of upper airway stabilization, whether by mechanical means and/or positive airway pressure therapy means. Pantino and Thornton do not even hint to such a connection.

8. The device disclosed in Thornton is intended to treat sleep disordered breathing such as snoring and sleep apnea using positive airway pressure therapy. The device is not intended to or disclosed in any way as being suitable for treating functional somatic syndromes. Until Dr. Gold's recent disclosure, the use of a CPAP device to treat functional somatic syndromes was unknown and, consequently, untried and such a device would not have been used by one skilled in the art to treat a functional somatic syndrome. It would be non-obvious to do so. As with Pantino, Thornton does not disclose or suggest a possible relationship between inspiratory airflow limitation during sleep and the functional somatic syndromes and, thus, provides no motivation for the use of positive airway pressure therapy in the treatment of functional somatic syndromes. As indicated previously, I find no reason to conclude that one having skill in the art would have been motivated to combine the CPAP system of Thornton with

the mechanical treatment of sleep disordered breathing in Pantino to treat a patient suffering from a functional somatic syndrome. It is only Dr. Gold's disclosure that identifies a causal connection between an inspiratory airflow limitation during sleep and the functional somatic syndromes and identifies a corrective remedy in the form of upper airway stabilization.

9. In summary, Pantino and Thornton provide no teaching or suggestion relating to a possible clinical connection between an inspiratory airflow limitation during sleep and the functional somatic syndromes as does Dr. Gold's Application. Accordingly, these patents do not in any way teach or suggest the suitability or desirability of either mandibular stabilization or continuous positive airway pressure therapy (or a combination thereof) in the treatment of functional somatic syndromes once inspiratory airflow limitation during sleep has been identified in a patient. One skilled in the art would not have recognized from either of these disclosures that upper airway stabilization may be valuable in treating the functional somatic syndromes once inspiratory airflow limitation during sleep has been determined without first consulting Dr. Gold's Application. Further, one having skill in the art with knowledge of Pantino and Thornton would not have been motivated to combine the CPAP device in Thornton with the mechanical treatment of sleep disordered breathing in Pantino to treat a patient identified as suffering from a functional somatic syndrome or symptom thereof for the reasons detailed previously in Paragraph 7 above.

10. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issuing thereon.

Signed Name: Mark H. Sanders

Typed Name: Mark H. Sanders, M.D.

Date: May 16, 2007

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,038	01/09/2004	Avram Reuben Gold	2111-040037	7887

28289 7590 08/16/2005

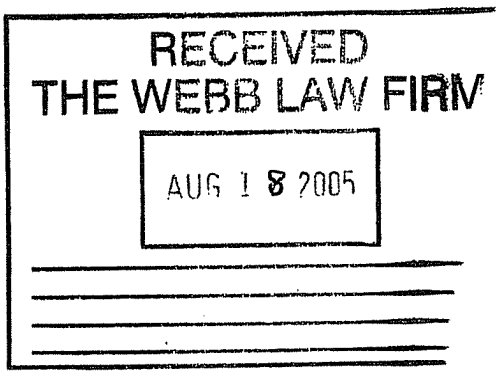
THE WEBB LAW FIRM, P.C.
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

EXAMINER	
ALEXANDER, JOHN D	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 08/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



Office Action Summary	Application No.	Applicant(s)	
	10/755,038	GOLD, AVRAM REUBEN	
	Examiner	Art Unit	
	John D. Alexander	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 9, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, drawn to a method of treating functional somatic syndromes, classified in class 600, subclass 26.

II. Claims 21-28, drawn to a method for diagnosing a sleep disorder, classified in class 607, subclass 42.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are different methods and are therefore independent and distinct.

Because these inventions are distinct for the reasons given above and the search required for Group 1 is not required for Group II, restriction for examination purposes as indicated is proper. For example, the search for Group I requires finding patient treatment via an airway stabilization technique, while the search for Group II does not require any provision of treatment.

Furthermore, this application contains claims directed to the following patentably distinct species of the claimed invention: embodiments 1 and 2 of treating functional somatic syndromes using and airway stabilization technique represented by identifying a patient as having a functional somatic syndrome (Claims 1-11) and identifying a patient as having one or more symptoms of functional somatic syndrome (Claims 12-20), respectively. Additionally, invention II and embodiments 1 and 2 of invention I each contain claims to two patentably distinct species for the treatment by airway stabilization technique: the species comprising mechanical stabilization (Claims 2-3, 13-14, or 25) and the species comprising positive airway pressure therapy (Claims 4-5, 15-16, or 26-27).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there are no claims that are allowable and generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Christian E. Schuster on August 11, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Alexander whose telephone number is (571) 272-8756. The examiner can normally be reached on Monday-Friday, 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDA

GEORGE R. EVANISKO
PRIMARY EXAMINER
6/17/5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/755,038	Confirmation No. :	7887
Applicant	:	Avram Reuben Gold		
Filed	:	January 9, 2004		
Title	:	METHOD OF TREATING FUNCTIONAL SOMATIC SYNDROMES AND DIAGNOSING SLEEP DISORDERS BASED ON FUNCTIONAL SOMATIC SYNDROME SYMPTOMS		
Group Art Unit	:	3739		
Examiner	:	John D. Alexander		

ELECTION WITH TRAVERSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

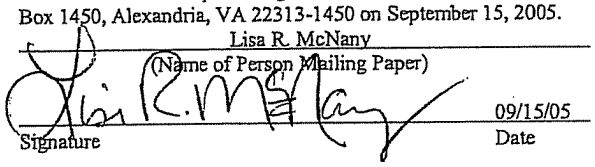
Sir:

In response to the requirements in the August 16, 2005 Office Action, Applicant hereby elects the claims of Group I, claims 1-20, for further prosecution in this application with traverse. Additionally, in response to the species election in the Office Action, Applicant hereby elects the positive airway pressure therapy species under Group I for further prosecution in this application. In addition to generic independent claims 1 and 12, Applicant believes that claims 4-11 and 15-20 from Group I are readable on the elected species. Claims 1, 6-12, and 17-20 are believed to be generic claims.

Remarks begin on page 2 herein.

I hereby certify that this paper or fee is being deposited with the United States Postal Service as first class mail in an envelope addressed to Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 15, 2005.

Lisa R. McNany
(Name of Person Mailing Paper)



Signature

09/15/05
Date

REMARKS

In the Office Action, restriction was required between the following groups of claims:

Group I - Claims 1-20, drawn to a method of treating functional somatic syndromes; and

Group II - Claims 21-28, drawn to a method for diagnosing a sleep disorder.

As indicated, Applicant elects claims 1-20 for further prosecution in this application. This restriction is respectfully traversed for the following reasons. While the Examiner's statement in the Office Action is true that independent claim 21 does not recite a treatment aspect of treating sleep disordered breathing in a patient, this claim does recite determining whether a patient suffers from one or more symptoms of a functional somatic syndrome. Independent claim 1, included in elected Group I, includes a generally analogous step of identifying a patient as having a functional somatic syndrome. To perform an adequate search of this feature set forth in independent claim 1 relating to identifying a patient as having a functional somatic syndrome, such a search will likely encompass the indicated step recited in independent claim 21 of determining whether a patient suffers from one or more symptoms of a functional somatic syndrome. The foregoing method steps recited in independent claims 1 and 21 will necessarily go hand-in-hand when the Examiner's search is performed. Accordingly, it is respectfully submitted that it would not place an undue burden on the Examiner to maintain the claims of Group II, claims 21-28, with the claims of Group I, claims 1-20, due to the synergy present between independent claims 1 and 21. Moreover, this will also result in the most efficient prosecution of the present application for the Examiner and the Applicant.

Applicant further notes that claims 22 and 23 of Group II include search terms similar to that set forth in claims 8-10 of Group I, (e.g., alpha-delta sleep and upper airway resistance syndrome (UARS) and obstructive sleep apnea/hypopnea (OSA/H)), so a search for the specific features set forth in claims 8-10 will likely encompass the similar

features set forth in claims 22 and 23. Additionally, dependent claims 24-28 of Group II relate to methods and apparatus for treating a patient with sleep disordered breathing, and are generally analogous to claim 1 (second recited method step) and claims 3-6 of Group I, respectively. Accordingly, there would be no additional burden on the Examiner by maintaining dependent claims 24-28 in the application with generally analogous claims 1 (second recited method step) and 3-6.

In the August 16, 2005 Office Action, there was also a species requirement in both Groups I and II relating to the claimed airway stabilization technique. In elected Group I, the species election is indicated by the Examiner as being between mechanical stabilization (claims 2, 3, and 13, 14) and positive airway pressure therapy (claims 4, 5 and 15, 16). As indicated previously, Applicant has elected the positive airway pressure therapy species for further prosecution in this application. The Examiner indicates on page 3 of the Office Action that no claims are considered generic. Applicant respectfully traverses the Examiner's conclusion, as independent claims 1 and 12 in Group I are presently generic to both species, each generally reciting "an airway stabilization technique" which clearly encompasses both positive airway pressure therapy and mechanical stabilization. In addition to independent claims 1 and 12, the following dependent claims are believed to be readable on the elected species (e.g., positive airway pressure therapy): claims 4-11 and 15-20. As indicated Applicant believes claims 1, 6-12, and 17-20 are generic claims.

As a complete search for the subject matter of independent claims 1 and 12 (e.g., "an airway stabilization technique") will likely encompass both mechanical stabilization and positive airway pressure therapy, it is respectfully submitted that maintaining both species in this application would not place an undue burden on the Examiner and expedite prosecution of this application. Accordingly, the Examiner is respectfully requested to maintain both species in this application and examine these species concurrently.

In view of the foregoing, Applicant respectfully requests examination of the claims of Group I, claims 1-20, and at least claims 4-11 and 15-20 readable on the elected species (e.g., positive airway pressure therapy). Applicant reserves the right to

file a divisional application on the non-elected claims of Group II, claims 21-28, and the non-elected species claims, namely claims 2, 13, and 14, should the Examiner maintain the restriction requirement in the next Office Action.

Respectfully submitted,

THE WEBB LAW FIRM

By _____

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APPENDIX D—RELATED PROCEEDINGS

NONE